

**1. 510(k) Summary****510(k) Summary**

[As required by 21 CFR 807.92(c)]

K963861  
DEC 18 1996**1.0 Submitter Information**

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1.3 Date Prepared: 24 September 1996

**2.0 Device Identification**

2.1 Trade Name: Lasershare Print Spooler and/or Software  
2.2 Common Name: Digital Imaging Network Spooler  
2.3 Classification Name: System, Digital Image Communication, accessory

**3.0 Predicate Devices**

Imageshare 910 [DeJarnette Research Systems, Inc.]  
SIENET CS Camera Server [Siemens Medical Systems, Inc.]  
MergeAPS (MergeMVP) [Merge Technologies, Inc.]  
Resource Spooler [Analogic Corporation]  
VIPStation [CEMAX, Inc.]

**4.0 Device Description****4.1 Function:**

The Lasershare Print Spooler is designed to accept images from various modalities or digital image networks and direct images to one or more medical imaging print devices, providing spooling and queue management facilities.

Core technology for the Lasershare Print Spooler is based on, and various software components ported from, the Imageshare 910 Protocol Converter (a predicate device). The Lasershare is a modular system that uses network interfaces for communication between the modules. Network interfaces enable the various modules to reside on local or remote machines.

**4.2 Physical and Performance Characteristics:**

The Lasershare Print Spooler and/or Software is designed to run on off-the-shelf, general purpose computing equipment. The application software is designed for maximum portability across operating systems and hardware platforms. Performance of the application software is primarily a function of network load; secondarily a function of the hardware platform's computational speed and finally the performance of the printer(s). Intrinsic performance of the application does not change significantly as it is ported from one operating system to another.

**5.0 Intended Use:**

The Lasershare Print Spooler and/or Software is a distributable filming management system that receives digital images and format control data from various image sources (including, but not limited to, CT scanners, MR scanners, Ultrasound systems, R/F units, Computed and Direct Radiography devices, secondary capture devices, imaging gateways, removable storage media or other imaging sources) connected point to point or via networks. The incoming data formats are standard medical imaging formats or proprietary to the modality source vendor. The Lasershare Print Spooler and/or Software allows the operator to manage print job requests, create filming sessions and route image and patient data to one or more laser film printers, thermal dye sublimation and dry printers and other medical imaging print devices.

**6.0 Statement of Substantial Equivalence:**

The Lasershare Print Spooler and/or Software is substantially equivalent to previously marketed devices (as listed above in Part 3) in design, composition, function, intended use, safety and efficacy.

Any differences between the Lasershare Print Spooler and/or Software and the predicate devices have no significant influence on safety or efficacy.